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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/242,343 04/12/99 VOLLENBROICH

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EXAMINER

BRUMBACK, B

ART UNIT

PAPER NUMBER

1642

10

DATE MAILED:

10/26/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/242,343

Applicant(s)
Vollenbroich et al.

Examiner
Brenda Brumback

Group Art Unit
1642



☒ Responsive to communication(s) filed on Sep 20, 2000

☒ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-17 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-17 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 3

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

1. This action is responsive to the amendment filed 09/20/2000. Claims 1-6 and 9-11 were amended. New claims 13-17 were added. Pending claims are 1-17.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

3. German patent DE19521938 submitted with the Information Disclosure Statement 04/12/99 has been considered pursuant to applicant's arguments filed 09/20/2000, which were persuasive. An updated copy of the IDS is attached hereto.

Claim Objections

4. The objection to claims 1-12 as lacking proper introduction is withdrawn subsequent to applicant's amendment of 09/20/2000.

Claim Rejections - 35 USC § 112

5. The rejection of claims 1-10 under 35 U.S.C. 112, first paragraph, as not enabled for inactivating viruses in biological compositions such as cell cultures using concentrations greater

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than 70 μ M is maintained. Applicant's amendment of claim 1 to recite that the lipopeptide is added to the culture medium is noted; however, claim 1 is still drawn to a method of inactivating lipid-enveloped viruses in cell cultures. Adding the lipopeptide to the culture medium bathing the cells would still expose the cells in culture to the lipopeptide at concentrations which the art teaches are lethal to cell cultures.

Additionally, newly added claims 13-16 are also rejected under 35 U.S.C. 112, first paragraph, for the reasons of record for original claims 1-10.

6. The rejection of claim 2 is rejected under 35 U.S.C. 112, first paragraph, as nonenabling for inactivation of viruses in biological compositions at 60°C is now moot because this limitation has been deleted from the rejected claim; however, applicant's arguments regarding the inactivation period of 5-30 min. are pertinent to newly added claim 13 and are persuasive.

7. The following rejections of claims 1-12 under 35 U.S.C. 112, second paragraph, are maintained.

The rejection of claim 1 as reciting biological and biotechnological products is withdrawn due to applicant's amendment thereof; however, claim 1 remains indefinite because it is unclear how cell cultures are to be distinguished from other biological products. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the

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metes and bounds of the patent protection desired. Claim 1 recites the broad recitation “biological products”, and the claim also recites “cell cultures” which is a narrower statement of the range/limitation.

The rejection of claim 10 for syntax and recitation of viruses by abbreviation only is withdrawn; however, the claim remains indefinite because the metes and bounds of “herpesviruses” and “immunodeficiency viruses” cannot be determined.

The rejection of claim 12 under 35 U.S.C. 112 and 101 for insufficient antecedent basis for “lipopeptides” and for recitation of a use without active method steps is maintained. Applicant’s statement (page 8 of the response filed 09/20/00) that “Claim 12 has been canceled ...” is noted; however, however claim 12 was not canceled in the response.

All other rejections of claims 1-12 under 35 U.S.C. 112, second paragraph, are withdrawn pursuant to applicant’s amendment thereof.

Claim Rejections - 35 USC § 103

8. The rejection of claims 1, 3, 4-7, 9, and 10 under 35 U.S.C. 103(a) as being unpatentable over Itokawa et al. is maintained. New claims 14-17 are also rejected under 35 U.S.C. 103(a) as being unpatentable over Itokawa et al. for the reasons of record. Applicant’s arguments filed 09/20/2000 have been fully considered but they are not persuasive.

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Applicant argues that the sole disclosure in Itokawa et al. regarding antiviral activity is at page 607. Itokawa et al. also teach anti-human immunodeficiency virus activity in the first sentence of the abstract (see page 604).

Applicant argues that based on the disclosure of moderate anti-HIV activity the one skilled in the art would be led away from using cyclic lipopeptides. The examiner can find no teaching in Itokawa et al. that teaches away from using cyclic lipopeptides for inactivation of lipid-enveloped viruses. A teaching of moderate anti-viral activity would rather point directly to their use.

Applicant argues that the moderate effects of Itokawa et al. are insufficient to safely inactivate viruses to the degree required for biological products for clinical use. In response to applicant's argument that Itokawa et al. fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., safety of biological products for clinical use) are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

9. The rejection of claims 1, 3, 9, and 10 under 35 U.S.C. 103(a) as being unpatentable over Naruse et al. is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that Naruse et al. teach inhibition of viral-induced cytopathic effects (CPE) after 72 hours, whereas the present method has an upper limit of 2 hours. The examiner

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disagrees. Naruse teaches incubation of cell cultures for 72 hours to allow sufficient time for formation of CPE as an indicator of HSV viability or inactivation. Naruse does not teach that inactivation of HSV requires inactivation with a cyclic lipopeptide for 72 hours. As was pointed out in the prior Office action, Naruse is silent as to the time required for actual virus inactivation. In fact, applicant's disclosure teaches incubating mixtures of SIV and surfactin for 14 days to allow for formation of SIV CPE, which is an even longer incubation period than that taught by Naruse (see page 29, #3).

Applicant argues that pumilacidins are lipoheptapeptides which are related to surfactins but differ in the length of their fatty acid components and have a higher cytotoxicity. Applicant's claims, however, are not drawn specifically to surfactins; they are drawn to cyclic lipopeptides. Naruse et al. teach cyclic lipoheptapeptides. Once again, applicant is arguing features which are not claimed.

10. The rejection of claim 2 under 35 U.S.C. 103(a) as being unpatentable over either Itokawa et al. or Naruse et al. in view of Horowitz et al. is maintained. Additionally, newly added claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over either Itokawa et al. or Naruse et al. in view of Horowitz et al. for the reasons of record. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that Horowitz et al. is irrelevant to the presently claimed method of inactivating lipid-enveloped viruses using lipopeptides because Horowitz et al. teach treating with

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fatty acid ligands for 10 hours. Applicant is arguing against the reference individually. As was pointed out in the prior Office action, the relevant teaching found in Horowitz is that raising the temperature accumulates viral inactivation in the presence of a detergent. One cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

11. The rejection of claims 8, 11, and 12 under 35 U.S.C. 103(a) as being unpatentable over the combined teachings of Itokawa and Naruse in view of Vater et al. is maintained. Applicant's arguments have been fully considered but they are not persuasive.

Applicant argues that there is no disclosure or suggestion in Vater et al. of the presently claimed method of inactivating lipid-enveloped viruses using cyclic peptides. Once again, applicant is arguing against the reference individually where the rejection is based on a combination of references. Vater et al. was cited as teaching mixtures of closely related variants of lipopeptides all having antiviral activity.

NEW GROUNDS OF REJECTION

Claim Objections

12. Claim 15 is objected to for an informality in grammar. The term "viruses" in line 1 should be amended to -- virus --.

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Conclusion

13. No claims are allowed.

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda Brumback whose telephone number is (703) 306-3220. If the examiner can not be reached, inquiries can be directed to Supervisory Patent Examiner Anthony Caputa whose telephone number is (703) 308-3995. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Examiner Brenda Brumback, Art Unit 1642 and should be marked "OFFICIAL" for entry into prosecution history or "DRAFT" for consideration by the examiner without entry. The Art Unit 1642 FAX telephone number is (703)-305-3014.

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Brenda Brumback
October 24, 2000



DONNA WORTMAN
PRIMARY EXAMINER